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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.

DATES: The meeting will be held on Wednesday, March 15, 2017, from 8:30 a.m. until 5:00 p.m. and Thursday, March 16, 2017, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FUTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; e-mail address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 8:30 a.m., on Wednesday, March 15, 2017, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Executive Secretary of SACHRP, and Dr. Stephen Rosenfeld, SACHRP Chair. Dr. Menikoff will then lead a discussion focusing on selected sections of the new Common Rule, which was published January 19, 2017, with an effective date of January 19, 2018 (see https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/html/2017-01058.htm).

The SOH will present their recommendations for considerations of the new Common Rule's compliance dates and transition provisions, as well as for the interpretation and implementation of the new broad consent provision.

The SAS will discuss their report on the interpretation of the new exemption involving benign behavioral interventions.

The Wednesday meeting will adjourn at approximately 5:00 p.m.

The Thursday, March 16, meeting will begin at 8:30 a.m. with recommendations from the SOH on the FDA Draft Guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices," issued July 27, 2016. SOH will also present recommendations on the return of incidental findings to research subjects. The SAS will present recommendations surrounding the new Common Rule's expedited review requirements.

The meeting will adjourn at 4:30 p.m. March 16, 2017. Time for public comment sessions will be allotted both days. Note that public comment must be relevant to issues being addressed by the SACHRP.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. On-site registration is required for participation in the live public comment session. Individuals who would like to submit written statements as public comment should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Dated: February 23, 2017

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Julia G. Gorey,

Executive Director,

Secretary's Advisory Committee on Human Research Protections

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